Programmatic Activity Report DUKE - Duke University -> 🗎

Editor:	Patrick Shanahan	
Activity Information		
Activity Type:	Programmatic On-site	Activity Date: 11/22/2013
Report Date:	12/19/2013	Closed Date: 12/19/2013
Report Attachment:	See Below	
Additional Notes & Grant Data:	PDE	
	Trip Report for Miranda (Duke_M	ichigan) 833293 Email 2013.pdf

Grant No (1st 8 positions):	83329301
Project Description:	The objective of the Southern Center on Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO) is to determine how environmental, social, and host factors jointly drive health disparities and birth outcomes. The Center will support the following three highly integrated studies: (1) a geographic information system based, statistics project; (2) a community-based birth cohort; and (3) a basic science animal model.

IGMS Post-Award Tracking Document ==> Post-Award Tracking

	V
Is payment history consistent with progress to date? Explanation:	Yes
2. Is the work under the agreement on schedule? Explanation:	Yes
Is the actual work being performed within the scope of the recipients workplan? Explanation:	Yes
4. Are the recipient's staff and facilities appropriate to handle the work under the agreement. Explanation:	Yes
5. Are the products/progress reports submitted on time? Explanation: The last report was 27 days overdue.	No
6. Are the products/progress reports acceptable? Explanation:	Yes
7: Is the recipient making adequate progress in achieving outcomes and outputs and associated milestones in the assistance agreement work plan? Explanation:	Yes
8: If the recipient is experiencing significant problems meeting agreed-upon outcomes and outputs, has the recipient been required to develop and implement a corrective action plan? Explanation:	N/A
9. Has the recipient complied with the programmatic terms and conditions on the award? (e.g., QMP, Human Subjects, Program Income, etc.) Explanation:	Yes
10. Did the recipient purchase equipment/property as planned in the agreement? Explanation: Orginally no equipment was budgetd for the grant; however, some funds were rebudgted to purchase equipment.	Yes
11. Has the equipment been used as planned in the agreement? Explanation:	Yes
12. Does this review indicate any need to amend the award? Explanation:	No
13. If this award includes sub-awards, is the recipient complying with the sub-award policy requirements? Explanation:	Yes

Attach Other Documentation Here:

PA Office of Research and Development National Center For Environmental Research Research Progress Evaluation Report

Background

On-Site Evaluation: (yes or no): Yes Off-Site Evaluation(yes or no): No

Date(s) of On-Site Evaluation/Off-Site Evaluation: 11/22/2013

Report Date: 12/19/2013

Project Officer (Contact): Richard Callan
Principal Investigator: Marie Lynn Miranda

Recipient Organization: Duke University and University of Michigan Grant Number / Cooperative Agreement Number: RD83329301

Project Title: Southern Center on Environmentally Driven Disparities in Birth Outcomes (SCEDDBO)

Solicitation/RFA Year: Centers for Children's Environmental Health and Disease Prevention Research

(2005)

Introduction, Background and Methodology:

[Give a brief description of the recipient and the project; describe the grant work-plan/narrative commitments; discuss previous recommendations if any exist.]

The Southern Center on Environmentally Driven Disparities in Birth Outcomes (SCEDDBO) is investigating how environmental, social, and individual factors interact and jointly impact the health of newborn children. Social conditions such as deteriorating housing, inadequate access to health care and high poverty can exacerbate environmental concerns like exposure to toxins and can lead to lower birth weights and premature births, which can impede lung and other organ development. SCEDDBO researchers seek to understand these factors and their influence, especially in low-income families, eventually leading to ways to prevent health problems during pregnancy and infancy. Field studies are combined with an extensive library of location-based data of the distribution of environmental contaminants to examine the causes and consequences of environmentally induced diseases in children. The Center has 3 linked projects and 2 Cores.

Research Project A is an epidemiological study, while Research Project B is a complementary clinical obstetrics project, and both projects focus on how combined environmental, social, and host factors shape disparities in birth outcomes. Research Project C uses a mouse model system to explore how disparities in exposure and response to exposure initiate and/or enhance disparities in birth outcomes and subsequent neonatal respiratory health. Project C also explores the effects of combined environmental exposures to prototypical air pollutants common in North Carolina (particulate matter and ozone) and non-chemical stressors on fetal growth restriction, neonatal somatic growth, and subsequent lung development and function.

The Center includes a Geographic Information Systems and Statistical Analysis (GISSA) Core and a Community Outreach and Translation Core (COTC).

Results of Review with Recommendations (success and findings):

[Address the Core Areas for Review: discuss equipment and personnel issues; review project progress (outputs/outcomes); discuss financial/expenditure issues; evaluate grantee's compliance with programmatic terms

and conditions and statutory/regulatory requirements (e.g., Human Subjects and Quality Assurance/Quality Control).

Equipment and Personnel

No equipment was budgeted for the grant although some funds were rebudgeted to purchase computer servers for the Center's GIS and data analysis needs.

There have been no recent changes in key personnel for this grant. One of the original investigators, Marcy Speer, director of the Duke Center for Human Genetics and an investigator on Project B, passed away in 2007.

Dr. Miranda became dean of the School of Natural Resources and Environment at the University of Michigan in January, 2012 and retains a faculty appointment at Duke and continues to provide scientific direction and leadership for the Center. She works closely with Center co-Director, Dr. Rick Auten, and Project Manager Pamela Maxson to see that SCEDDBO objectives are achieved.

Project Progress (Outputs/Outcomes)

The recipient is making excellent progress in achieving the outputs and outcomes as detailed in the assistance agreement workplan. Monthly Center meetings are held via conference calls or in person.

Nineteen years of data from North Carolina Detailed Birth Records have been integrated and standardized to facilitate data linkages and statistical analysis. GIS analysts at the University of Michigan are geocoding administrative and clinical datasests and updating them as new data are released.

Project A, "Mapping Disparities in Birth Outcomes," is investigating whether exposures to socioeconomic and air pollution contribute to racial and ethnic health disparities in infant birth outcomes. The researchers have developed methods to output predictive surfaces of ozone and PM_{2.5} at the census-tract level covering the state of North Carolina in order to understand the environmental justice dimension of air pollution exposure, and have linked this to records on birth outcomes to examine the joint effects of socioeconomic status and air pollution on birth outcomes. One recently published study found that maternal prenatal smoking may interact with birth outcomes on reading and mathematics test scores, particularly among non-Hispanic white children.

Project B, "Healthy Pregnancy, Healthy Baby: Studying Racial Disparities in Birth Outcomes," is investigating how the interaction of environmental, social, and host factors contribute to racial disparities in birth outcomes between African-American and white women. Participant recruitment has been completed, with nearly 2000 women enrolled, including many most at risk for adverse pregnancy outcomes, including low-income and non-Hispanic, African-American women. The investigators have been highly successful in collection of participant-level data as well as biological samples, while more than 940 delivery samples of cord blood and placenta have been collected. All maternal data are georeferenced (linked to the physical address of the mother) using GIS software and there are in-depth neighborhood assessments in place. The investigators have completed analyses on psychosocial influences on birth outcomes. New statistical methodologies have been developed to improve data analysis and uncovered an interaction between women who smoke and who have high blood lead levels tend to have babies with lower birth weights.

Project C, "Perinatal Environmental Exposure Disparity and Neonatal Respiratory Health," is using a mouse model to determine whether maternal exposure to airborne particulate matter (PM), ozone or a combination restricts fetal growth or growth after birth. The investigators are looking at the effects of prenatal exposure to diesel exhaust on neurocognitive development and finding that a postnatal high fat diet or prenatal maternal social stress shows synergistic effects on impairment of cognitive development in mice, and the effects on microglial activation appear to be dependent on toll-like reception 4 (TLR4).

b) (6), (b) (4)

Financial/Expenditures

The payment history is consistent with the progress to date. A two-year, no-cost extension was approved in 2012. The extension was needed to allow the investigators to complete data and statistical analysis. Additional time was also needed under Project A to obtain 2010 birth record data, analysis of the data on the built environment and pregnancy outcomes and to complete geocoding data. For Project B, additional time was also needed to connect the data with psychosocial, genetic and physical health of mothers and infants in the clinical project, finish developing and validating statistical methods, characterize the interactions between host, social and environmental factors that might influence pregnancy outcomes, compile results, prepare manuscripts and disseminate information to the community. For Project C, additional time was also needed for data analysis to determine the window of vulnerability for maternal inhalation exposure to particulate matter and diesel exhaust that may worsen the effects of postnatal ozone on airway hyperreactivity and on lung structure and to understand the nature of responses to diesel exhaust. They also needed additional time to complete their analyses of altered immune response pathways on postnatal lung structure and function. The remaining funds are sufficient to complete the work by the time the extension ends on April 30th, 2014.

A subaward to the University of Michigan was approved in 2012 to provide support to Dr. Miranda, two statisticians, two GIS analysts and related expenses for supplies, travel, retreats/meetings and to maintain the SCEDDBO website. Additional funding for Project A has been obtained from NIH and the Duke Institute for Brain Sciences.

Programmatic Terms and Conditions

Programmatic terms and conditions are being met except that the 2013 progress report was about 27 days late. The reports are well written and comprehensive and are acceptable in format, length and content.

Statutory/Regulatory Requirements

All statutory and regulatory requirements are being met.

QA/QC: The PO is satisfied that adequate QA/QC procedures are in place. A Quality Management Plan (QMP) is in place and has been approved, Dr. Pamela Maxson is the QA Manager and the plan is being followed. Each staff person receives a copy of the QMP and is asked to reaffirm her/his commitment to quality assurance and the QMP.

Subagreement: The subagreement's scope and statement of work is consistent with the approved assistance agreement workplan and subagreement costs are eligible and allowable. The recipient has not rebudgeted any funds to contracting.

Human Subjects and Animal Subjects: The recipient has complied with the regulations regarding research with human subjects under 40 CFR Part 26, and has complied with the

Duke_UMich RD83329301 EvalProtocol 112213.doc

Findings				
None		Payroll	Problems	Property Management Finding
Possible Conflict	of Interest	☐ No Trave		Property Management Findings Indirect Costs Issues
Possible Lobbyin	a		mented Cost Share	
☐ No Accounting M	J		Controls Missing	Labor Distribution Findings
	rement Procedures	-	s Reports	 Cash Management Subrecipient/Contract Monitoring
	Conflict of Interest Police			Results not being achieved
☐ No Cost or Price			Assurance	Environmental Results Findings
Commingling of F	The state of the s	A-133 A		
Unallowable Cost			pliance with Terms and Co	Other / please explain in below text a
Evplanatory Toyte				
Explanatory Text:				
Action Against Recip	pient:			
No Action Require	ed		IG Referral	
Recipient Placed	on Reimbursement		On-Site Refer	ral
Special Award Te	rms and Conditions (at	tach below)		Corrective Action Required (attach specifics below
Stop Work Issued		,		ies (attach specifics below)
Award (s) Termin			office recinion	les (attach specifics below)
Specifics: (Enter or a	ttach additional informa	tion as needed.)	
Validation Information	1			
Validation Date:	01/07/2014	Validated By:	Nicole Roberts	
Recipient Point of Co	ntact			
Project Manager: Title:	Marie Miranda			
E-Mail:			Phone:	
Address:	Some in the second			
City: State:	Durham			
Other Recipient Info/Comments:			Zip:	
EPA Contact Informat	ion			
EPA Lead:	Patrick Shanahan			

E-Mail:

Shanahan.Patrick@epa.gov

Phone:

EPA Office		
EPA Region: HQ	AAShip: ORD - Office of Research and Development	Division: NCER
U Other Participants:	Richard Callan	

Document Review

Compass Document: GO RD83329301

01/16/14

Document Summary: General Ledger Entries Doc Type: GO Doc No: RD83329301 Vendor Code: 560532129A V IGMS Grant No: 83329301-5 IGMS Budget Start Date: 05/01/2007 IGMS Budget End Date: 04/30/2014 IGMS Project Start Date: 05/01/2007 IGMS Project End Date: 04/30/2014 Order Date: 04/25/07 Closed Date:

Closed Date: Servicing Finance Office: LVFC Order Amount: \$7,735,637.00 Net Paid Amount: \$7,604,566.88 Closed Amount: \$7,604,566.88 Available Amount: \$131,070.12 Vendor: DUKE UNIVERSITY Alternate Vendor: Description: CONVERSION **Extended Description:**

Document Details: Expand							
	(b) (4)	und	Org	Program	Project	FOC CostOr	Comments
			26T4000	404FB2D		4141	RQ 0726TJ0347
			26T40NN	405FB2D	n/a	4141	RQ 0726TJ0347
			26UJ000	404FB2D	n/a	4141	RQ 0826UJRR08
			26T4000	404FB2DPV	n/a	4141	RQ 0826TG0893
			26T4000	404FB2DPV	n/a	4141	RQ 0926T1X060
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Document Activity:

Warehouse Homepage FPA@Work Home | EPA Internet

http://V1742TRTAY003.aa.ad.epa.gov/neis/grant_web grant_result

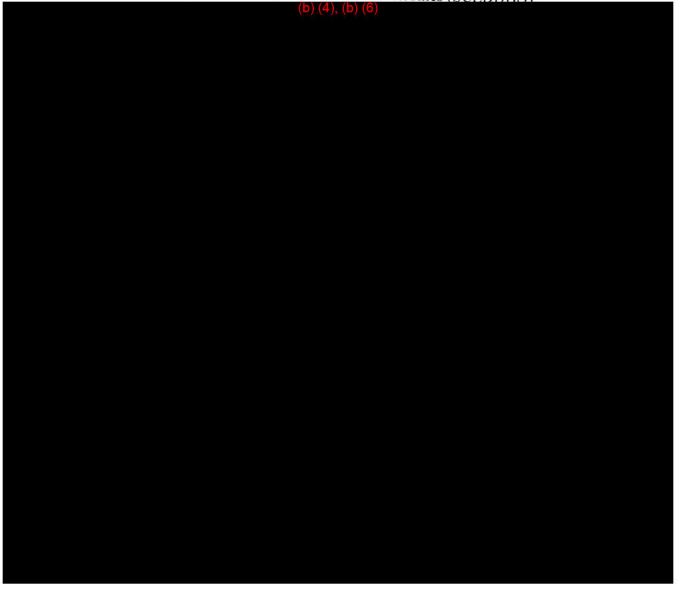
This web page was last updated on 08/11/2012.

For issues, please contact: The OCFO Sytem Help Desk - OCFO-System-Help@epa.gov or (202) 564-OCFO (6236)

ADDENDUM TO:

ORD EPA Project Officer Post-Award Evaluation Protocol for EPA STAR Grant RD83329301 to Duke University and the University of Michigan, PI: Marie Lynn Miranda, for the Southern Center on Environmentally Driven Disparities in Birth Outcomes (SCEDDBO)

(b) (4), (b) (6)



ND83329301 DUNG/MICHIGAN CONT 11/2013

ORD EPA PROJECT OFFICER POST-AWARD EVALUATION PROTOCOL 1/08/2008

ject Officer Off-Site/On-Site Review Guidance and Protocol

ke the administrative reviews conducted by the Grants Management Offices (i.e., those which focus on the recipient institution=s financial onnel, property and procurement records, systems and procedures), Project Officers are responsible for performing programmatic review those which pertain to the goals, objectives and activities reflected in the assistance agreement).

Site Evaluation: A review conducted at the recipient's facility of the programmatic performance of the grant, including compliance with is and conditions of the agreement, research progress, and certain regulatory requirements, and documented with a report.

Site Evaluation: A review of the recipient's programmatic performance of the grant, including compliance with terms and conditions of the research progress, and certain regulatory requirements, and documented with a report. By definition, an off-site evaluation occur y from the recipient's facility or performance site and may be accomplished in a number of ways, such as by telephone conference or facility at meetings or workshops.

OR TO CONDUCTING THE ON-SITE OR OFF-SITE EVALUATION, Project Officers must:

- Review the workplan (including quality assurance requirements) under the signed assistance agreement, the recipient=s progress reports and any products produced under the agreement to date
- Review the Federal role under the agreement (including the collaborative activities, schedules, comments and approvals for which the Project Officer had the responsibility)
- \$ Identify the issues that require resolution during the visit
- \$ Confirm the date and scope of review with the Principal Investigator (PI)
- Review the recipient=s grant payment history at http://oasint.rtpnc.epa.gov/neis/grant_web.grant_inquiry to help assess whe the recipient=s progress is commensurate with payments made by EPA
- \$ Assess whether the recipient is meeting programmatic reporting requirements
- \$ Gather all pertinent information for the visit

FER THE EVALUATION, Project Officers must:

- \$ File a report which:
 - \$ Summarizes Project Officer observations and conclusions in each of the core review areas
 - \$ Explains how the issues were resolved during the review
 - \$ Discusses how and when outstanding issues will be resolved
 - \$ Includes milestones and next steps
- Notify the PI of any findings, resolved and unresolved issues and EPA/recipient commitments
- Work with the grants office to initiate any necessary grant amendments (e.g., scope or budget revisions)
- Seek and document assistance from senior management or the grants office for unresolved issues

STRONGLY RECOMMENDED that Project Officers use this document in their efforts to develop a report.

nsure that progress is being made to meet the original goal and objective of the assistance agreement and that activities are carried out ording to applicable statutes, regulations, and policies, Project Officers must contact their Grants Office immediately if the recipient show as an agreement. If there is reason to believe that the recipient has mitted or commits fraud, waste and/or abuse, then the Project Officer must contact the Office of the Inspector General.

questions regarding this document, please contact your office point of contact.

BACKGROUND INFORMATION

TYPE OF EVALUATION:
⊠On-Site Evaluation
□Off-Site Evaluation
DATE(S) OF EVALUATION: 11/22/2013
GRANT NUMBER: RD83329301
PROJECT OFFICER: Richard Callan
PRINCIPAL INVESTIGATOR: Marie Lynn Miranda
RECIPIENT ORGANIZATION: Duke University and University of Michigan
BUDGET/PROJECT PERIOD: 5/01/2007-4/30/2014
AWARD AMOUNT: \$7,735,637

REVIEW QUESTIONS

1. Financial	The PO should determine if		
		YES	NO
Project Officers are responsible for:	the payment history is consistent with the progress to date.		
 Reviewing the payment history 			1
(using recipient progress reports			
and IFMS grant inquiry) and			
comparing actual amounts spent against the planned budget and			
current progress.	additional funds are required to meet the		
 Providing rebudgeting approval to 	objectives.		
the Grants Specialist on the			
recipient's request to rebudget			
grant funds or on actions which			
require prior approval from EPA.			
2. Technical	The PO should determine if	YES	<u>NO</u>
Project Officers are responsible for:	75 W W W		
	the work under the agreement is on	\boxtimes	
 Monitoring all activities and the 	schedule.	201 C 2018*1	20-20
recipient's progress on the project.	2		
Providing comments to the	the work being performed is within the	\boxtimes	
recipient on progress reports and other work products.	scope of the workplan.		
other work products.			

 Assessing the recipient's progress in achieving the outputs and outcomes set forth in the assistance 	project milestones are being metthe recipient is making progress in achieving outputs & outcomes (to the maximum extent practicable) set forth in the	\boxtimes	
 agreement workplan. Apprising program staff who are responsible for parts of the project/program on issues which need resolution. 	assistance agreement workplan. the recipient is experiencing significant problems meeting agreed upon outcomes and outputs.		
Recommending actions that require the attention of the Grants Office, the Office of General Counsel, and their Quality Assurance Manager/Officer.	the recipient has been required to develop and implement a corrective action plan (if "yes" was answered on the previous question).		
	the products/progress reports are being submitted on time.	Not Due	
			\boxtimes
	the products/progress reports are acceptable.	Not Due	
	ассеріавіе.	\boxtimes	
	the staff and facilities are appropriate to handle the work under the agreement.	\boxtimes	
	any changes were made to key personnel.		\boxtimes
3. Agreement Specific	As Appropriate, the PO should determine if		
Project Officers are responsible for:	PROGRAM REGULATIONS/TERMS and	YES	<u>NO</u>
 Reviewing progress reports and other work products to assure that the recipient is complying with the applicable regulations and the 	CONDITIONSthe recipient has complied with the agreement's relevant programmatic regulations and programmatic terms and conditions.	\boxtimes	
programmatic terms and conditions	EQUIPMENT	N/A	\boxtimes
of the agreement. Notifying the grants office if the		YES	<u>NO</u>
 Notifying the grants office if the recipient is not complying with the terms and conditions of the agreement. 	the recipient purchased equipment as planned in the agreement.		
	the equipment has been used as planned in the agreement.		

			No.
Providing technical assistance to	TD ALVEL	27/4	
 Providing technical assistance to recipients when requested or 	TRAVEL	N/A YES	NO
required by the programmatic		IES	NO
terms and conditions of the award.	authorized travel is being carried out.		
Although it is not required, Project	CONFERENCES/WORKSHOPS	N/A	
Officers should, if applicable:		YES	NO
 Share relevant information from the November 1998 Best Practices Guide for Conferences and the Office of 	the conference/workshop complied with the Best Practices Guide for Conferences (e.g., conference was not for EPA's direct benefit/use, EPA did not control agenda, location, or speakers)	\boxtimes	
General Counsel's Printing	SUBAGREEMENTS	N/A	
Guidance (June 14, 2000) with the recipient.		YES	NO
 Work with the recipient to ensure that the work under a subagreement (e.g., contracts, 	subagreement's scope/statement of work is consistent with the approved assistance agreement workplan.		
subgrants, memoranda of understanding, and, if applicable, intergovernmental agreements under the assistance agreement) does not	the recipient rebudgeted funds to contracting.		
go beyond the scope of the assistance agreement.	subagreement costs are eligible and allowable.	\boxtimes	
Notes:	HUMAN SUBJECTS	N/A	
 Select those areas which apply 		YES	<u>NO</u>
to your specific agreement: Equipment, Travel,	the recipient has complied with the regulations under 40 CFR Part 26.	\boxtimes	
Conferences/Workshops,	ANIMAL SUBJECTS	N/A	
Subagreements, Human Subjects, Animal Subjects, and	Alexander and the second Policy of the second	YES	<u>NO</u>
Quality Assurance/Quality Control.	the recipient has complied with the Animal Welfare Act and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.	\boxtimes	
	QUALITY ASSURANCE/QUALITY	N/A	
	CONTROL	YES	<u>NO</u>
	an approved Quality Management Plan (QMP) or Quality Assurance Project Plan (QAPP) [or equivalent QA documentation described in the terms and conditions of the agreement] is in place.	\boxtimes	

	all personnel responsible for implementing the QA documentation (including operating procedures) are familiar with the requirements and are implementing them as written.				
	there is an assessment tool and schedule to ensure that all QA/QC requirements and procedures are met.	\boxtimes			
OBSERVATIONS and CONCLUSIONS The Southern Center on Environmentally Driven Disparities in Birth Outcomes (SCEDDBO) is part of the EPA/NIEHS Children's Centers program and the only Children's Center funded exclusively by EPA. In November, 2013, I traveled to Duke University in North Carolina and spoke with Principal Investigator Marie Lynn Miranda and Center co-Director Richard Auten and visited laboratory facilities. Professor Miranda is currently the Dean of the School of Natural Resources and Environment at the University of Michigan and retains a faculty appointment at Duke, and some of the staff is located at Duke and some in Michigan. The Center is in no-cost extension and work at the Center is proceeding very well and they have achieved many of their specific aims. (b) (4), (b) (6)					

AREAS REQUIRING SENIOR MANAGEMENT OR GRANTS OFFICE ASSISTANCE	
None.	
EVALUATOR'S NAME	Richard Callan
DATE	12/19/2013